## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE.

Confirmation No · 9269 In re-Werner et al Appl No.: 10/535,763 Group Art Unit: 1638 Filed: May 20, 2005 Examiner: Page, Brent T.

For: METHOD OF CONTROLLING A CELLULAR PROCESS IN A MULTI-

CELLULAR ORGANISM

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## RESPONSE TO RESTRICTION REQUIREMENT

This is in response to the Office Action dated October 18, 2007, in which the Examiner has required restriction between Group I, namely Claims 1-6 in part and 9-31, Group II, namely Claims 1-6 in part and 7-31, and Group III, namely Claims 32-34. The Office Action indicates that this supplemental restriction was needed "in order to clarify the invention." The Examiner further requires that if Applicants elect Group I or II, the further election of:

- (a) a protein portion from among those set forth in claims 19-22 and one origin of the peptide:
- (b) an external signal that causes expression from among a small molecular compound. metal ions, a polypeptide, a protein, a nucleic acid, a pathogen, a bacterium, a virus, a fungus, light, or temperature change, and if Applicants elect a polypeptide as the external signal, the Examiner requires the further election of one pathogenic organism for application of polypeptide from among either virulent Agrobacterium, nonvirulent Agrobacterium, virulent bacteria with type-III secretion signal, non-virulent bacteria with type-III secretion signal or one of virulent or non-virulent Bordetella, Erwinia, or Pseudomonas or Xanthomonas, or Yersinia; and
- (c) the type of transformation from either stable integration into genome, stable integration into plasmid, or transient transformation.

Finally, the Examiner requires Applicants to indicate which claims are believed to read on the elected invention.

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Applicants hereby provisionally elect with traverse to prosecute the claims of Group 1 (Claims 1-6 in part and 9-31) for a viral movement protein or vial coat protein (i.e., claim 19), a polypeptide external signal, virulent Agrobacterium as the microorganism, and stable transformation into the genome for the introduction of the heterologous nucleic acid. Applicants believe that claims 1-6, 9-14, 17-19, 23, and 25-31 read on the elected invention.

Applicants expressly reserve the right to file one or more divisional applications or take such other appropriate measures deemed necessary to protect the inventions in the remaining claims and in the non-elected subject matter of the elected claims.

Applicants, however, respectfully disagree with the Restriction Requirement because the application, in contrast to the position stated the Office Action, does not lack unity of invention for the reasons set forth below. Therefore, Applicants respectfully request that the Examiner reconsider the requirement for restriction and examine all of the claims together in the present application

The Office Action indicates that the inventions of Groups I-III<sup>1</sup> do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, the inventions of Groups I-III lack the same or corresponding technical features. The Office Action indicates on page 2 that the inventions of Groups I-III "are related by the technical feature of a protein that is a signal for causing the expression of a protein, this feature is not special since it does not constitute an advance over the prior art." The Office Action indicates that WO 95/21248 teaches "an MP protein that is applied exogenously to facilitate protein expression and cell-to-cell movement in a multi-cellular organism." The Office Action further indicates that each Group has functions and components that are not required by the other Group and may be used for different processes.

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<sup>&</sup>lt;sup>1</sup> The Office Action mailed October 18, 2007 states on page 2 that "[t]he inventions listed as Groups I-II do not relate to a single general inventive concept..." (emphasis added). Applicants assume for the purposes of the present response that the Examiner intended to indicate that Groups I-III do not relate to a single general inventive concept. If Applicants' assumption is incorrect, Applicants request a further opportunity to address the requirement for restriction after the Office issues a new Office Action to clarify further the basis for the requirement for restriction.

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Applicants respectfully disagree with the positions of the Office Action that: (1) the inventions of Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because the inventions of Groups I-III lack the same or corresponding technical features. and (2) Applicants' invention does not constitute an advance over the prior art, namely WO 95/21248. In contrast to the view of the Office Action, Applicants submit that the three independent claims, claims 1, 27, and 32 are novel and inventive over WO 95/21248 because this document fails to disclose the method of claim 1, the multi-cellular organism produced by said method (claim 27), and the composition of claim 32. Claims 1 and 27 and their respective dependent claims, each involve the same or corresponding technical features, particularly a protein that is capable of leaving a cell and entering other cells of an organism (item (i) of claim 1; item (b) of claim 27) and causing expression of said protein in cells containing the heterologous nucleic acid encoding said protein (item (ii) of claim 1; item (c) of claim 27). Claim 32 relates to this same or corresponding technical feature in that claim 32 is directed to a composition for external application to a multi-cellular organism, wherein the composition contains a protein or polypeptide that is a signal for causing expression of a protein in the multicellular organism of claim 27, particularly a protein that is capable of leaving a cell and entering other cells of an organism and causing expression of said protein in cells containing the heterologous nucleic acid encoding said protein. WO 95/21248 fails to disclose such a method, multi-cellular organism, or composition involving these same or corresponding technical features of Applicants' claimed invention. Accordingly, the instant application meets the unity of invention requirement of PCT Rule 13.1.

Concerning the position of Office Action that each Group has functions and components that are not required by the other Group and may be used for different processes, Applicants respectfully remind the Examiner that unity of invention practice, not restriction practice, applies to the present U.S. national stage application according to MPEP § 1893.03(d). See also, 37 C.F.R. § 1.499 (2007). Unity of invention is defined in 37 C.F.R. § 1.475(a) (2007) which provides that the "application shall relate to one invention only or to a group of inventions so

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linked as to form a single general inventive concept ('requirement of unity of invention')." As discussed in detail above, the instant application meets the requirement of unity of invention.

For the above reasons, Applicants submit that the Restriction Requirement is improper and should be withdrawn because the present application relates to a single general inventive concept under PCT Rule 13.1 and therefore, satisfies the requirement of unity of invention. Accordingly, Applicants respectfully request that the Examiner examine all of the claims together in the instant application.

Should the Examiner have further questions or comments with respect to examination of this case, it is respectfully requested that the Examiner telephone the undersigned so that further examination of this application can be expedited.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those, which may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted, /david m. saravitz/

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